

Amendments to and Listing of the Claims:

Please amend claims 19-24, 27, 28 and 32-34, without prejudice or disclaimer, cancel claims 35 and 36, without prejudice or disclaimer, as set forth in the following listing of the claims, which will replace all prior versions, and listings, of claims in the application:

1 – 18. (Cancelled)

19. (Currently Amended) A non-human transgenic mammal selected from the group consisting of mice, rats, goats, pigs, sheep and cows, whose genome comprises:

(a) an α -lactalbumin (α -LA) promoter; and

(b) a nucleotide sequence linked to the α -LA promoter, the nucleotide sequence encoding a recombinant polypeptide comprising a ~~mammary gland~~milk-specific signal peptide and a mature polypeptide of a B-domain deleted human clotting factor VIII (FVIII) polypeptide lacking its innate signal peptide,

wherein the non-human transgenic mammal ~~secretes~~secretes the B-domain deleted human FVIII polypeptide in milk when the mammal is lactating.

20. (Currently Amended) The non-human transgenic mammal of claim 19, wherein the ~~mammary gland~~milk-specific signal peptide is a ~~the~~ bovine α -LA signal peptide of SEQ ID NO:13.

21. (Currently Amended) The non-human transgenic mammal of claim 20, wherein the bovine α -LA signal peptide is encoded by a ~~the~~ DNA sequence of SEQ ID NO: 1.

22. (Currently Amended) The non-human transgenic mammal of claim 19, wherein the mammary gland-specific signal peptide is a ~~the~~ bovine α -S1 casein signal peptide of SEQ ID NO:14.

23. (Currently Amended) The non-human transgenic mammal of claim 22, wherein the bovine α -S1 casein signal peptide is encoded by a ~~the~~ DNA sequence of SEQ ID NO: 2.

24. (Currently Amended) The non-human transgenic mammal of claim 22, wherein the recombinant polypeptide comprises a ~~an~~ the amino acid sequence of SEQ ID NO: 15.

25. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the B-domain deleted human FVIII polypeptide is proteolytically processed intracellularly into a light chain having the A3, C1 and C2 domains and a heavy chain having the A1 and A2 domains, wherein the light chain and heavy chain are operably linked by a junction.

26. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the α -LA promoter is a 2.0-kb bovine α -LA promoter.

27. (Currently Amended) The non-human transgenic mammal of claim 19, producing up to about 50 mg of the B-domain deleted human FVIII polypeptide per ~~litter~~-liter of milk when the non-human transgenic mammal is lactating.

28. (Currently Amended) A method for making the non-human transgenic mammal of claim 1, the method comprising:

(a) introducing into an embryo of a mammal a transgene comprising

(i) the α -LA promoter; and

(ii) the nucleotide sequence linked to the α -LA promoter;

(b) implanting the embryo into a female of the same species as the ~~non-human transgenic mammal~~ embryo; and

(c) permitting the embryo to develop into the non-human transgenic mammal of claim 1.

29. (Previously Presented) The method of claim 28, further comprising confirming the presence of the transgene in the non-human transgenic mammal by polymerase chain reaction (PCR) analysis.

30. (Previously Presented) The method of claim 28, further comprising confirming the expression of the transgene in the non-human transgenic mammal by reverse transcription PCR analysis.

31. (Previously Presented) The method of claim 28, further comprising analyzing milk from the non-human transgenic mammal for the B-domain deleted human FVIII polypeptide.

32. (Currently Amended, Withdrawn) Milk collected from the non-human transgenic mammal of claim 19, wherein the milk comprises the B-domain deleted human FVIII polypeptide.

33. (Currently Amended, Withdrawn) Milk collected from the non-human transgenic mammal of claim 22, wherein the milk comprises the B-domain deleted human FVIII polypeptide.

34. (Currently Amended, Withdrawn) The milk of claim 32 comprising up to about 50 mg of the B-domain deleted human FVIII polypeptide per liter of the milk.

35. (Cancelled)

36. (Cancelled)